510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

A.	Company Name:	Invivo Corporation
B.	Company Address:	12601 Research Parkway Orlando, FL 32826
C.	Company Phone: Company Fax:	(407) 275-3220 (407) 206-9658
D.	Contact Person:	John Racette Quality Assurance and Regulatory Affairs Manager Invivo Corporation
E.	Date Summary Prepared:	December 2, 2005

DEVICE IDENTIFICATION

A.	Generic Device Name:	MRI compatible multiparameter patient monitor
B.	Trade/Proprietary Name:	3160 MRI Patient Monitor
C.	Classification:	Class II
D.	Product Codes:	

Classification Names		Code	CFR Ref
1.	Monitor, Cardiac	DRT	870.2300
2.	Monitor, Blood Pressure, Non-Invasive	DXN	870.1130
3.	Oximeter	DQA	870.2700
4.	Analyzer, Gas, Carbon Dioxide, Gaseous Phase	CCK	868.1400
5.	Analyzer, Gas, Enflurane, Gaseous Phase	CBQ	868.1500
6.	Analyzer, Gas, Halothane, Gaseous Phase	CBS	868.1620
7.	Analyzer, Gas, Nitrous Oxide, Gaseous Phase	CBR	868.1700
8.	Analyzer, Gas, Oxygen, Gaseous Phase	CCL	868.1720
9.	Blood Pressure Computer (Invasive Blood Pressure)	DSK	870.1110
10.	Thermometer, Electronic, Clinical	FLL	880.2910
11.	Monitor, Breathing Frequency	BZQ	868.2375
12.	Monitor, physiological, patient	MWI	870.2300

DEVICE DESCRIPTION

The 3160 MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. It is designed to assist clinicians in monitoring patient vital signs in the midst of the dynamic and evolving Magnetic Resonance environment.

A combination of wireless communication, radio frequency (RF) shielding, digital signal processing (DSP), and adaptable mounting technologies address the challenges associated with patient monitoring in the MRI area. Built on Invivo's strong heritage in MRI patient vital signs monitoring, the 3160 MRI Patient Monitoring System provides accurate, continuous, and reliable performance during all phase of MRI applications.

SUBSTANTIAL EQUIVALENCE

The 3160 MRI Patient Monitoring System is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
3160 MRI Patient Monitoring System	Invivo Research, Inc.	K050399	08/26/05
Magnitude 3150/3155 MRI Patient Monitoring System	Invivo Research, Inc.	K040915	09/22/04
Integrated Patient Monitoring System	Invivo Research, Inc.	K041918	10/15/04
Polaris 2004 Capnograph	Oridion Medical Ltd	K040011	05/13/04

INTENDED USE

The 3160 MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The 3160 MRI Patient Monitoring System is intended for use by health care professionals.

COMPARISON TO PREDICATE DEVICE:

The primary differences between this device and the predicate 3160 MRI Patient Monitoring System are as follows:

- The end-tidal CO2 monitoring option is the same as that incorporated into the predicate 3160 MRI Patient Monitoring System (K050399), except that
  - the sensor is smaller, which in turns allows for a smaller flow rate,
  - the detector material has been changed from a thermopile to zinc selenium,
  - one detector is used to read both the patient gas and the baseline reference.

  This same technology is used in the Oridion Medical Ltd Polaris 2004 Capnograph, which was cleared to market under 510(k) K040011.
- The invasive blood pressure monitoring option is exactly the same as that used in the Magnitude™ MRI Monitoring System (K040915).
- The temperature monitoring option is exactly the same as that used in the Magnitude™ MRI Monitoring System (K040915).
- The respiration monitoring option is exactly the same as that used in the Integrated Patient Monitoring System, which was cleared to market under 510(k) K041918.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the 3160 MRI Patient Monitoring System and the predicate devices has been performed. The results of this comparison demonstrate that the 3160 MRI Patient Monitoring System is equivalent to the marketed predicate devices in technological characteristics.

ENVIRONMENTAL AND NON-CLINICAL TESTING:

Applicable environmental and non-clinical testing was performed per UL60601 and EN IEC 60601-1-2 as well as other applicable particular standards and procedures. The 3160 MRI Patient Monitoring System passed all tests.

PERFORMANCE DATA

The performance data included in this submission to compare equivalency of the Magnitude 3150/3155 MRI Patient Monitoring System and the Integrated Patient Monitoring System 510(k) cleared devices to the modified 3160 MRI Patient Monitoring System met the performance requirements for accuracy and precision and indicates substantial equivalence to the predicate devices. Equivalent performance in meeting user requirements was also determined.

Summary of Performance Testing:
Validation and Verification Testing confirmed that the modified device operates as designed and intended. A summary of this testing is as follows:

This device was validated using a 3.0T MRI System as a worst-case environment. These devices were validated by verifying proper operation of the device while being subjected to 3.0T magnetic fields using simulators and test equipment under actual use conditions. Two scans, TRUE-FISP and PLANAR-ECHO, were used in both magnetic fields to simulate normal and worst-case MRI conditions.

End Tidal CO2 Monitoring (Capnometer)		
Parameter	**Specification**	**Pass/Fail**
Measurement Range	0-76 mmHg	Pass
Accuracy	±2mmHg + 5% of reading	Pass
Flow Rate	50 mL/min	Pass
Respiration Rate	0 to 100 BPM	Pass
Zero Drift Rate	0.5 mmHg/hr; 1.5 mmHg/24hr	Pass
Alarm Limits	Lower: Off, 5 to 60 mmHg Upper: Off, 5 to 80 mmHg	Pass
Inspired CO_2	25 mmHg	Pass

Invasive Pressure Monitoring		
Parameter	**Specification**	**Pass/Fail**
Channels	1 or 2 simultaneous channels	Pass
Bandwidth (-3dB)	0 to 12 Hz	Pass
Range	-10 to +248 mmHg	Pass
Sensitivity	5 uV/V/mmHg	Pass
Gain Accuracy	± 0.5 %	Pass
Auto Zero Feature	Zeroes with +/- 300 mmHg offset to 0+/- 5 mmHg within 1 second	Pass
Waveform Display Scales	0 to 45, 0 to 75, 0 to 150, 0 to 200, 0 to 250 mmHg	Pass
High Pressure Alarm	5 to 248 mmHg range; 1 mmHg resolution	Pass
Low Pressure Alarm	5 to 248 mmHg range; 1 mmHg resolution	Pass

Temperature Monitoring		
Parameter	**Specification**	**Pass/Fail**
Temperature Range	25 to 44°C (77° to 111.2°F)	Pass
Accuracy	± 0.5°C (± 0.5°F)	Pass
Resolution	± 0.1°C (± 0.18°F)	Pass

Respiration Monitoring		
Parameter	**Specification**	**Pass/Fail**
Range	4 to 150 BPM	Pass
Resolution	1 BPM	Pass
Accuracy	2% to 60 BPM, 3.4% at 87 BPM, 5.6% at 142 BPM	Pass

Conclusion:

The verification and validation activities for the 3160 MRI Patient Monitoring System confirm that all identified risks have been mitigated and that this device operates as designed and intended. The test results demonstrate the revised 3160 MRI Patient Monitoring System is substantially equivalent to the device cleared to market via 510(k) \ K050399 and the other predicate devices identified in this submittal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

Invivo Corporation
c/o Mr. John Racette
Quality Assurance and Regulatory Affairs Manager
12601 Research Parkway
Orlando, FL 32826

Re: K053462
Trade Name: 3160 MRI Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor
Regulatory Class: Class II (two)
Product Code: MWI
Dated: December 6, 2005
Received: December 13, 2005

Dear Mr. Racette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053462

Device Name: **3160 MRI Patient Monitoring System**

Indications for Use:

The 3160 MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The 3160 MRI Patient Monitoring System is intended for use by health care professionals.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vehmeyer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053462